IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

SONIA MONTIEL and CAROL NUNES-MCNAMARA, on behalf of themselves and all others similarly situated, Plaintiff, vs. DAVOL, INC., and C.R. BARD, INC. Defendants.	CA 07 064ML CASE NO. CLASS ACTION **CLASS ACTION COMPLAINT AND JURY DEMAND**

Plaintiffs, Sonia Montiel and Carol Nunes-McNamara, by their attorneys, bring this action individually and on behalf of all others similarly situated, and allege the following, upon information and belief:

NATURE OF THE ACTION

1. Plaintiffs bring this action on behalf of themselves and the Class defined herein against C.R. Bard, Inc. (hereinafter "Bard") and its wholly owned subsidiary, Davol, Inc., (hereinafter "Davol"), for their sale and distribution of defective Composix Kugel Mesh Patches. The Defendants' defective product has been surgically implanted into the bodies of the Plaintiffs and the class members. The patch presents, and will continue to present, a substantial risk of injury or death to the Plaintiffs and the Class Members. As a result, Plaintiffs and the class have been injured and will need continual and ongoing medical monitoring.

PARTIES

2. Plaintiff Sonia Montiel ("Sonia") is an individual citizen and resident of the State of Illinois. During the relevant time period, Sonia had hernia repair surgery which included the

implantation of a Composix Kugel Mesh Patch into her body. That patch remains in her body to this day.

3. Plaintiff Carol Nunes-McNamara ("Carol") is an individual citizen and resident of the State of California. During the relevant time period, Carol had hernia repair surgery which included the implantation of a Composix Kugel Mesh Patch into her body. That patch remains in her body to this day.

4. Defendant Davol Inc. (hereinafter "Davol") is and was a wholly owned subsidiary of Bard, with its principal place of business at 100 Sockanosset Crossroads, P.O. Box 8500, Cranston, Rhode Island, 02920. At all times relevant, Davol was a corporation duly organized and existing under the laws of the State of Delaware, with its principal place of business for manufacturing hernia surgical repair products in Cranston, Rhode Island. Davol designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of Rhode Island.

5. Defendant Bard is a New Jersey corporation with its principal office and place of business at 730 Central Avenue, Murray Hill, New Jersey, 07974, and at all times relevant designed, manufactured, tested, analyzed, distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners, certain hernia surgical repair products to be surgically implanted in patients throughout the United States, including the State of Rhode Island.

JURISDICTION AND VENUE

6. This Court has diversity jurisdiction over the Class pursuant to 28 U.S.C. §§ 1332(d)(2) and (6) of the Class Action Fairness Act of 2005. Plaintiff and each member of the putative Class have suffered aggregate damages exceeding five million dollars ($5,000,000), exclusive of interest and costs. There are members of the Class who are citizens of a different State than Defendants.

7. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(a) because Plaintiff resides in this judicial district, Davol maintains its principal place of business in this district and earns substantial compensation and profits from its sales of products in question in this district. Also, a substantial part of the events giving rise to the claims at issue arose in this district.

GENERAL ALLEGATIONS

8. This class action involves the Composix Kugel Mesh Patch manufactured by Defendants between 2001 and March 2006. These Composix Kugel Mesh Patches were sold by Defendants for implantation in patients in the course of hernia repair surgery.

9. A hernia occurs when the stomach muscles are too weak to contain the intestines, and as a result, a rupture occurs in the muscle wall which allows the intestines to protrude. The Composix Kugel Mesh Patch was designed to treat ventral hernias caused by the thinning or stretching of scar tissue that forms after surgery.

10. The Kugel Mesh line of products was first manufactured by Surgical Sense, Inc., starting in or around 1996. In January of 2000, Bard acquired the Kugel line of hernia repair products from Surgical Sense, Inc. Shortly thereafter, in 2001, Bard introduced the Composix Kugel Mesh Patch through its subsidiary, Davol.

11. The Composix Kugel Mesh Patch, invented by Dr. Robert D. Kugel, is a polypropylene mesh prosthetic device developed to repair ventral hernias, or hernias of the abdominal region. The Composix Kugel Mesh Patch is inserted behind the hernia defect in the abdomen through a small incision. In order to fit through the small incision the mesh is folded in half. Once inside the abdomen the mesh re-deploys as a result of a hard "memory recoil ring" (or "PET coil ring") that surrounds the mesh.

12. Due to defects in the design and manufacturing of the Composix Kugel Mesh Patch, the "memory recoil ring" that opens the patch can break under the stress of placement of the product in the intra-abdominal space. Once the memory recoil ring has broken, it can later come loose and cause serious injuries as it travels through the body. These injuries include: intestinal perforations; ring migration through the abdominal wall; abscesses; bowel obstruction and sepsis; and chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

13. The Composix Kugel Mesh Patches present and constitute an unreasonable risk of danger and injury in the following respects:

a. the memory recoil ring of the Composix Kugel Mesh Patch is likely to malfunction after being implanted;

b. the Composix Kugel Mesh Patch was not properly manufactured;

c. the Composix Kugel Mesh Patch was defectively designed;

d. the Composix Kugel Mesh Patch did not perform as safely as an ordinary consumer/patient would expect;

e. the Composix Kugel Mesh Patch was inadequate or insufficient to maintain its integrity during normal use after implantation in the consumer/patient; and

f. such further and additional defects as discovery and the evidence reveal.

14. As a result of this dangerous and defective condition, and the numerous serious injuries that have resulted, the FDA issued Class 1 recalls of the X-Large Oval, Large Oval and Large Circle varieties of the Composix Kugel Mesh Patch. A Class 1 recall is the highest level of recall available to the FDA. It is issued when the FDA believes a medical product is dangerous or defective and predictably could cause serious health problems or death.

15. On December 22, 2005 and January 13, 2006, Davol and Bard announced the recall of the Composix Kugel Mesh X-Large patch. Subsequently, in March of 2006, the Defendants announced the recall of the Composix Kugel Mesh Large Patch as well.

16. Under these FDA recalls, the following products were subject to recall:

PC#0010206	Bard Composix Kugel	Extra Large Oval	8.7" x 10.7"
PC#0010207	Bard Composix Kugel	Extra Large Oval	10.8" x 13.7"
PC#0010208	Bard Composix Kugel	Extra Large Oval	7.7" x 9.7"
PC#0010209	Bard Composix Kugel	Large Oval	6.3" x 12.3"
PC#0010202	Bard Composix Kugel	Large Oval	5.4" x 7"
PC#0010204	Bard Composix Kugel	Large Circle	4.5"

17. The products that are affected by the recall were distributed to customers and implanted in patients worldwide. As of March 2006, roughly 75,000 Composix Kugel Mesh Patches had been sold. Upon information and belief, the vast majority of the patches which have been implanted are currently still inside patients residing in the United States.

18. At all times herein mentioned, Defendants knew, or in the exercise of reasonable care should have known, that the aforesaid products were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined,

sold, supplied, prepared and/or provided with proper warnings, were not suitable for the purpose they were intended and were unreasonably likely to injure the products' users.

19. Defendants' Composix Kugel Mesh Patches are uniformly defective because they possess the same potential for breakage or malfunction of the memory recoil ring and, as a result, are subject to risk of resulting injury.

20. Defendants did not timely apprise the public and physicians of the defect in their Composix Kugel Mesh Patches, despite Defendant's knowledge that memory recoil rings had failed due to the described defects. Defendants' concealment of a known defect from Plaintiffs and Class members equitably tolls any applicable statutes of limitation. No member of the Class could have discovered the existence of the defect in the implanted Composix Kugel Mesh Patches until at least December 27, 2005, when Defendants first began to provide notice of the recall.

21. Defendant's conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of the Plaintiffs and the members of the Class.

22. As a direct and proximate cause of Defendants' conduct and the recalled Composix Kugel Mesh Patches, Plaintiffs and the Class have suffered injuries and will require continual medical monitoring and care. Accordingly, Plaintiffs and the Class will incur future medical costs related to the recalled Composix Kugel Mesh Patches.

NAMED PLAINTIFFS' EXPERIENCE

23. Sonia underwent a hernia repair surgical procedure on December 13, 2004 at MacNeal Hospital located in Berwyn, Illinois, and, during the course thereof, Sonia's physician implanted a Composix Kugel Mesh Patch into her body.

24. Carol underwent a hernia repair surgical procedure on October 30, 2003 at Kaiser Permanente Medical Center located in Roseville, California, and, during the course thereof, Carol's physician implanted a Composix Kugel Mesh Patch into her body.

25. The Composix Kugel Mesh Patches implanted in Sonia and Carol were designed, manufactured, sold and distributed by Defendants, and were intended to be used by surgeons for hernia repair surgeries. Defendants represented these Composix Kugel Mesh Patches to be appropriate and suitable products for such purposes.

26. The Composix Kugel Mesh Patches in Sonia's and Carol's bodies present a serious ongoing health risk due to their defective design and/or manufacture.

27. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Composix Kugel Mesh Patch, Sonia has sustained, and will continue to sustain, injuries and damages, including, but not limited to, medical monitoring by means of a CT scan every 3 months.

28. As a direct and proximate result of Defendants' defective design, manufacture, function and/or inadequate warnings regarding the Composix Kugel Mesh Patch, Carol has sustained, and will continue to sustain, injuries and damages, including, but not limited to, medical monitoring.

CLASS ACTION ALLEGATIONS

29. Plaintiffs bring this class action on behalf of themselves and on behalf of all others similarly situated, as members of a proposed nationwide plaintiff class (the "Class") defined as follows defined as:

> All citizens, residents or domiciliaries of the United States who have had a recalled Composix Kugel Mesh Patch implanted into their person, which has not been explanted, and who have not developed a manifest and diagnosed injury as a result of the product of a degree or severity that would permit individual personal injury lawsuits to be commenced in their state of residence, but will require medical monitoring.

This action is brought and may properly be maintained as a class action pursuant to the provisions of Rule 23(a)(1)-(4), 23(b)(2), and 23(b)(3). This action satisfies the numerosity, commonality, typicality, adequacy, predominance and superiority requirements of Rule 23.

30. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or amended complaint. Specifically excluded from the proposed Class are Defendants, their officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint venturers, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or their officers and/or directors, or any of them; the Judge assigned to this action, and any member of the Judge's immediate family.

31. The Class is so numerous that the individual joinder of all its members is impracticable. While the exact number and identification of Class members are unknown to Plaintiff at this time and can only be ascertained through appropriate discovery of Defendants. On information and belief, Defendants have sold roughly 75,000 defective units, as such, the Class includes tens of thousands of class members.

32. Common questions of fact and law exist as to all members of the Class which predominate over any questions affecting only individual members of the Class. These common legal and factual questions, which do not vary from Class member to Class member, and which may be determined without reference to the individual circumstances of any Class member, include, but are not limited to, the following:

a. whether there are design and/or manufacturing defects in the Composix Kugel Mesh Patch;

b. whether Defendants failed to follow U.S. Food & Drug Administration ("FDA") good manufacturing practices, failed to properly investigate manifestations of the Composix Kugel Mesh Patch over the past several years, failed to adequately document reports of the defect, and failed to exercise adequate quality control;

c. whether Defendants' conduct in designing, manufacturing, marketing and monitoring the Composix Kugel Mesh Patch fell below the duty of care owed by Defendants to Plaintiff, Plaintiff's participants, and Class members;

d. whether Defendants intentionally, knowingly, carelessly, recklessly, or negligently concealed information regarding the existence of a defect in the Composix Kugel Mesh Patch from the FDA, physicians, Plaintiffs' members, and the members of the Class;

e. whether Composix Kugel Mesh Patch listed in the proposed Class definition share a common and inherent design defect that causes them to break, creating a risk of injury or death to patients in whom they were implanted;

f. whether Defendants negligently, recklessly, or intentionally misrepresented the quality and usefulness of the Composix Kugel Mesh Patch;

g. whether Defendants are liable for selling a dangerously defective product;

h. whether the Class has been injured by virtue of the Defendant's deceptive business practices and conduct;

i. whether the Class is entitled to injunctive and other equitable relief including restitution and disgorgement and, if so, the nature of such relief;

j. whether the Class is entitled to medical monitoring and treatment, at Defendant's expense; and

l. whether Defendants are liable for punitive or exemplary damages, and if so, the amount necessary and appropriate to punish Defendants for their conduct, to deter others, and to fulfill the other policies and purposes of punitive and exemplary damages.

33. Plaintiffs' claims are typical of the claims of the members of the Class. Plaintiffs and the members of the Class have suffered similar injury and are facing further damages arising out of Defendants' common course of conduct, as alleged herein. The economic losses of each Class member were and are caused directly by Defendants' conduct, as alleged herein. Plaintiffs and the members of the Class must prove the same facts in order to establish the same claims, as described herein, which apply to all Class members.

34. Plaintiffs are adequate representatives of the Class because they have been billed for the Composix Kugel Mesh Patch and medical costs relating to such devices, and will continue to incur related medical expenses, and their interests do not conflict with the interests of the members of the Class they seek to represent. Plaintiffs have retained experienced and competent counsel, and together Plaintiffs and counsel intend to prosecute this action vigorously for the benefit of the Class. The interests of the Class members will fairly and adequately be protected by Plaintiffs and their counsel.

35. A class action is superior to other available methods for the fair and efficient adjudication of this litigation because individual litigation of the claims of all Class members is impracticable. Even if every Class member could afford individual litigation, the court system could not. It would be unduly burdensome to the courts in which individual litigation of thousands of cases would proceed. Individual litigation presents a potential for inconsistent or contradictory judgments, and the prospect of a race for the courthouse, and an inequitable

allocation of recovery among those with equally meritorious claims. Individual litigation increases the expense and delay to all parties and the court system in resolving the legal and factual issues common to all Composix Kugel Mesh Patch claims. By contrast, the Rule 23 class action device presents far fewer management difficulties and provides the benefit of a single adjudication, economies of scale, and comprehensive supervision by a single court.

36. The various claims asserted in this action are additionally or alternatively certifiable under the provisions of Rule 23(b)(1) and/or (b)(2) because:

a. the prosecution of separate actions by thousands of individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members, thus establishing incompatible standards of conduct for Defendants;

b. the prosecution of separate actions by individual Class members would also create the risk of adjudication with respect to them that would, as a practical matter, be dispositive of the interests of the other Class members who are not a party to such adjudications and would substantially impair or impede the ability of such non-party Class members to protect their interests; and

c. Defendants have acted or refused to act on grounds generally applicable to the entire Class, thereby making appropriate final declaratory and injunctive relief with respect to the Class as a whole.

COUNT I

(Unfair And Deceptive Trade Practices Under Rhode Island State Law)

37. Plaintiffs reallege and incorporate by reference each and every allegation contained in this Complaint as though fully set forth herein.

38. At all times relevant, Defendants were engaged in the design, manufacturing, assembling, distributing, conveying and/or selling of the Composix Kugel Mesh Patch in their ordinary course of business. Defendants designed, manufactured, assembled and sold the devices

to hospitals and physicians, knowing that they would be thereby sold to patients who needed hernia repair surgery, including Plaintiffs and all other members of the Class.

39. Defendants had a statutory duty to refrain from unfair or deceptive acts or practices in the design, development, manufacture, promotion and sale of the Composix Kugel Mesh Patches.

40. Plaintiffs and the Class are consumers of the defective product and were injured by Defendants' deceptive and unfair acts.

41. Had the Defendants not engaged in the deceptive conduct described above, Plaintiffs and members of the Class would not have purchased and/or paid for the Composix Kugel Mesh Patches, would not have incurred related medical costs and would not continue to incur these costs.

42. Defendants' representations and material omissions to patients, physicians and consumers, including Plaintiffs and Class members, constituted unfair and deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, et. seq.

43. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiffs and Class members for the Composix Kugel Mesh Patches and/or for the costs of replacing the Composix Kugel Mesh Patches that they would not have paid had Defendants not engaged in unfair and deceptive conduct.

44. Plaintiffs and the Class were injured by the cumulative and indivisible nature of Defendants' conduct. The purpose of that conduct, directed at patients, physicians and consumers, was to create demand for and sell the Composix Kugel Mesh Patches. Each aspect of Defendants' conduct combined to artificially create sales of the Composix Kugel Mesh Patches.

45. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class have incurred and will likely continue to incur medical costs relating to the Composix Kugel Mesh Patch, including medical monitoring and/or other hospital costs, in an amount to be proven at trial.

46. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class are entitled to injunctive relief in the form of a court supervised medical monitoring program, punitive damages, attorneys' fees, and costs of suit.

47. Medical monitoring is medically reasonable and necessary in order to provide for the early detection and prevention of irreparable harm, severe and debilitating injuries and death. In the absence of such relief, Plaintiffs and the members of the Class might not receive prompt medical care that could prolong their productive lives, increase prospects for improvement and to minimize disability.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, pray for judgment against Defendants as follows:

1. For an Order certifying the Class and any appropriate subclasses thereof under the appropriate provisions of Rule 23, and appointing Plaintiffs and their counsel to represent the Class;

2. For an Order establishing a medical monitoring program, funded by Defendants, to provide medical testing, screening, services, research and education and a medical/legal registry to ensure that the Class members receive prompt and proper medical treatment;

3. For punitive or exemplary damages against Defendants where appropriate, in an amount sufficient to punish Defendants and deter others from similar wrongdoing;

4. For all applicable statutory damages under the consumer protection legislation;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest and the costs of suit; and

7. For such other and further relief as this court may deem just and proper.

JURY DEMAND

Plaintiffs on behalf of themselves and all others similarly situated, hereby demands a trial by jury in this case.

Dated: February 13, 2007

Donald A. Migliori (#4936)
MOTLEY RICE LLC
321 South Main Street
P.O. Box 6067
Providence, RI 02940-6067
401-457-7700
401-457-7708 FAX

Teresa C. Toriseva
Nancy C. Wilkins
WEXLER TORISEVA WALLACE LLP
1446 National Road
Wheeling, WV
304-238-0066
304-238-0149 FAX

Edward A. Wallace
Mark R. Miller
WEXLER TORISEVA WALLACE LLP
One North LaSalle Street, Suite 2000
Chicago, Illinois 60602
312-346-2222
312-346-0022 FAX

Fred Thompson, III
Rhett D. Klok
Fred Thompson
Henry Leventis
Carmen Scott
MOTLEY RICE LLC
28 Bridgeside Blvd.
P.O. Box 1792
Mt. Pleasant, SC 29465
843-216-9000
843-216- 9450 FAX